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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,324	09/29/2003	Mark B. Knudson	14283.1USI3	4634

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P.O. Box 2903
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EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,324

Applicant(s)

KNUDSON ET AL.

Examiner

Jessica L. Reidel

Art Unit

3766

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 12-15 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on September 21, 2006. Claims 1-11 and 16-19 have been cancelled. Claims 12-15 are pending.

Specification

2. The specification contains some references to commonly owned patent applications without application numbers or the current status of each referenced application. The Examiner respectfully requests that this information be updated along with any other referenced applications without application numbers or referenced applications that have since issued.

Claim Objections

3. Claim 12 is objected to because of the following informalities: there appears to be a typographical error in the 9th and 11th lines of the claim. At line 9, the Examiner suggests changing "blocking side on a distal to said stimulation site" to read "blocking site distal to said stimulation site" instead so as to clarify the claim language. At line 11, the Examiner suggests changing "block nerve impulses on said vagus nerves" to read "block nerve impulses on said vagus nerve" in order to avoid an antecedent basis problem. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3766

5. Claims 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by King (U.S. 6,928,320). As to Claim 12, King expressly discloses a method for treating peristalsis of a patient's esophagus and/or emptying a patient's stomach comprising electrically stimulating a vagus nerve 46 of the patient at a stimulation site (via electrodes 33 and 34) with a low frequency stimulation signal selected to have a therapeutic effect on the stomach 35, innervated by the stimulation site of the vagus nerve 46, applying a first electrical blocking signal to the vagus nerve 46 at a first blocking site (via electrode 32) proximal to the stimulation site and applying a second electrical blocking signal to the vagus nerve 46 at a second blocking site (via electrode 39) distal to the stimulation site (see King Fig. 7 and column 8, lines 27-55). King also expressly discloses that each of the first and second blocking signals are selected to at least partially block nerve impulses on the vagus nerve 46 at the first and second blocking sites (see King Abstract, column 3, lines 5-67, column 4, lines 1-37 and columns 5-6).

6. As to Claim 13, King specifies that the first and second high frequency blocking signals are variable (i.e. they are ramped up and ramped down) by an implantable pulse generator, read as a controller 114 (see King Fig. 3A and columns 5-6).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Osorio et al. (U.S. 6,341,236) (herein Osorio). King specifies that the target organ is the

Art Unit: 3766

stomach 35. King discloses the claimed invention as discussed above except that it is not specified that the method include sensing a physiologic parameter of a heart and regulating the controller in response to the sensed parameter.

Osorio, however, teaches that it is well known in the art that vagal stimulation has the undesirable side effect of altering the heart rate of a patient (see Osorio column 1, lines 62-667 and column 1-55). Osorio further specifies that it is also known, when applying stimulation signals or blocking signals to a vagus nerve, to sense a physiologic parameter of the heart and to regulate the vagal stimulation and/or blocking in response to the sensed parameter in order to minimize such undesirable side effects. Osorio discloses a method comprising electrically stimulating a vagus nerve 60 of a patient at a stimulation site with a stimulation signal selected to have a therapeutic effect on a target organ (i.e. the brain) while applying an electrically blocking signal (i.e. anodal currents or high frequency stimulation) to the vagus nerve 60 at a blocking site (anode of the electrode pair) on a side of the stimulation site opposite the target organ (i.e. the brain) where the blocking signal is selected to at least partially block nerve impulses to a second organ (i.e. the heart 55) on a side of the blocking site opposite the stimulation site (cathode of the electrode pair) (see Osorio Fig. 12A, column 6, lines 53-67 and column 7, lines 1-61). Osorio further discloses that a signal generator 20 may be used to vary the pulsing parameters of the pulse signal applied to the vagus nerve 60 (see Osorio column 5, lines 13-34 and lines 47-54). Osorio further discloses that physiological signals sensed via sensor 15 of the heart 55 may be used to regulate the pulse signal applied to the vagus nerve 60 (see Osorio column 3, lines 9-11 and lines 35-42 and column 4, lines 45-65). Osorio is considered to be synonymous with King in that they both involve vagal nerve stimulation and/or blocking. It would have been obvious to

Art Unit: 3766

one having ordinary skill in the art at the time the invention was made to modify the method of King to include the steps of sensing a physiologic parameter of a heart and regulating the controller in response to the sensed parameter in order to minimize the adverse side effects modulation of the vagal nerve is known to cause, such as an undesirable decrease in heart rate.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

Art Unit: 3766

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jessica L. Reidel 11/06/06
Examiner
Art Unit 3766


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766